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SECTION 2 – 510(k) SUMMARY

NOV 07 2008

Healix Ti Anchor

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767
Contact Person	Kristine Christo Regulatory Affairs Project Lead DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 Telephone: 508-828-3359 Facsimile: 508-828-3750 e-mail: KChristo@Dpyus.jnj.com
Name of Medical Device	Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners Common/Usual Name: Bone Anchor Proprietary Name: Healix Ti Anchor
Substantial Equivalence	Healix Ti Anchor is substantially equivalent to: Mitek Healix Anchor K071481(Aug 9, 2007) Fastin RC Anchor K060664,K0041075 (June 6, 2006; Nov 9, 2004). Super QA+ Anchor K052631 (Oct 21, 2005) Orthocord, violet (size #2) suture, K040004 (April 13, 2004) Orthocord blue (size #2) suture, K043298 (Dec 10, 2004). The Healix Ti Anchor is also similar to the Arthrex Corkscrew FT Anchor (K061863 and K061665) and the Arthrex Biocorkscrew Anchor (K061863 and K043337).
Device Classification	This device carries an FDA product code MBI and HWC, and is classified as Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners under 21 CFR 888.3040.

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Device Description	The Healix Ti Anchor is a non-absorbable threaded suture anchor manufactured of Titanium material. The threaded anchor comes preloaded on a disposable inserter assembly and is intended for fixation of #2 suture to bone. The anchor is provided in three sizes: one with an outer diameter of 4.5mm, another with an outer diameter of 5.5mm and the third with an outer diameter of 6.5mm. The suture options may or may not include tapered needles to facilitate suture passage through tissue. The Healix Anchors are currently offered with absorbable Panacryl, non-absorbable Ethibond or partially absorbable Orthocord suture options.
Indications for Use	**The Healix Ti Anchor** is intended for: **Shoulder:** Rotor Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction; **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair; **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Patella tendon repair and secondary fixation in ACL / PCL reconstruction repair. **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction. **Hip:** Capsular repair, acetabular labral repair.
Safety and Performance	Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Healix Ti Anchor has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

DePuy Mitek
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% Ms. Kristine Christo
Regulatory Affairs Project Lead
325 Paramount Drive
Raynham, Massachusetts 02767

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Re: K082282
Trade/Device Name: Healix Ti Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, JDR
Dated: August 8, 2008
Received: August 11, 2008

Dear Ms. Christo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K082282

Device Name: Healix Ti Anchor

Healix Anchor is indicated for use in the following:

Shoulder: Rotor Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis,
Patella tendon repair and secondary fixation in ACL / PCL reconstruction

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hip: Capsular repair, acetabular labral repair.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082282

Prescription Use √ OR Over-the -Counter Use ___
(Per 21 CFR 801.109)